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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,964	12/30/2005	Janel Birk	17957A US-PCT (HEA)	4253
51957	7590	08/20/2009	EXAMINER	
ALLERGAN, INC.			RANADE, DIVA	
2525 DUPONT DRIVE, T2-7H				
IRVINE, CA 92612-1599				
			ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			08/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,964	BIRK ET AL.	
	Examiner	Art Unit	
	DIVA RANADE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/19/09, 03/16/09, 06/24/08, 06/16/08, 12/30/05</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 39 and 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites the deployment tool including a transmission for transmitting movement of an actuator. The specification recites, on page 18, 'a transmission using gearing or other well known means' as the only explanation of the transmission for the deployment tool. This description of the invention is not full, clear or in exact terms as to enable one with ordinary skill in the art to make or use the invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 39-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over

US Patent 5,833,398 to Hinchliffe et al in view of U.S Patent 4,781,680 to Redmond et

al.

a. Claims 39, 48 and 57: Hinchliffe shows an implantable injection port and deployment tool system, comprising:

an implantable injection port comprising a housing with a port, the port includes a fastener (32) incorporated into the housing (28) to enable a user to attach the port to tissue without sutures, the fastener having an undeployed position and a deployed position, the deployed position extending below a lower face of the port opposite the upper face (See Column 7 lines 64-67 and Column 8 lines 1-7); and a deployment tool (12) having a proximal shaft and a distal cover (28) defining a recess that receives the port therein such that the lower face of the port (34) is exposed, the cover (26 See Fig 1) and recess being oriented to extend down over the port generally vertically, the proximal shaft extending upward from the distal cover at an angle to the vertical and having a proximal manual actuator, the

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tool including a transmission in the shaft for transmitting movement of the actuator through elements in the shaft capable of amplifying the force in order to function at a location distal from the point of actuation (See Fig 4) to the port for moving the fastener from its undeployed position to its deployed position and anchoring the port to tissue (See Column 5 lines 36-47) but lacks a septum retained by the housing, one end of the septum forming an upper face of the port generally oriented in a plane perpendicular to a vertical axis, the septum being capable of penetration by a needle along the vertical axis, the port further including a space below the septum defining a fluid reservoir and an outlet conduit through the housing from the reservoir. Redmond shows a septum (18) for use with a subcutaneous access site. The septum is resealable and would provide a more sterile and uncontaminated internal environment during surgery for piercing and injecting the site while performing a procedure. Therefore, it would have been obvious to one skilled in the art during the time of the invention to include a septum to the housing of Hinchliffe thereby creating a reservoir in order to provide a more sterile surgical environment. On type of actuator is the palm grip actuator. Furthermore as in claim 57, the actuator of Hinchliffe is pressed prior to shifting, therefore it would have been obvious to one with ordinary skill in the art to pivot the buttons in order to create a one step process of actuation wherein pressing with move the distal object further without the need to slide the buttons down.

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- b. Claims 40 and 49: Hinchliffe shows the deployment tool is activated via a pencil-grip actuator, a palm-grip actuator or a pistol-grip actuator (See Fig 1).
- c. Claims 41, 50 and 58: Hinchliffe shows the fastener pivotally rotates in the housing from the undeployed position to the deployed position (See Fig 26 and 27).
- d. Claims 42, 51 and 59: Hinchliffe shows wherein the transmission converts motion of the manual actuator into rotational motion about the vertical axis to cause the fastener to rotate (See Column 5 lines 46-67 and Column 6 lines 1-6).
- e. Claims 43, 52 and 60: Hinchliffe shows wherein the fastener pivotally rotates in the housing from the undeployed position to the deployed position (See Fig 26) the port further comprises a rotating disc for rotating the fastener from the undeployed position to the deployed position, and wherein the deployment tool contacts and rotates the rotating disc (See Column 11 lines 37-59, the rotating disc is the disc that rotates the fasteners from the undeployed to the deployed position. In this case the anvil comprises a camming surface which deforms the prongs rotating them radially inward.
- f. Claims 44, 53 and 61: Hinchliffe shows wherein there are a plurality of the fasteners in the form of curved hooks distributed around the lower face of the port that each pivot from the undeployed position to the deployed position (See Fig 26).

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g. Claims 45, 54 and 62: Hinchliffe shows wherein sharp tips of the curved hooks rotate through an arc and are received back in or near the lower face of the port at the end of their travel (See Fig 26).

h. Claims 46, 55 and 63: Hinchliffe shows wherein there are a plurality of the fasteners in the form of curved hooks distributed around the lower face of the port that each pivot from the undeployed position to the deployed position (See Fig 26).

i. Claims 47, 56 and 64: Hinchliffe shows wherein sharp tips of the curved hooks rotate through an arc and are received back in or near the lower face of the port at the end of their travel (See Fig 26).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DIVA RANADE/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763